Participation in European agencies: Keeping promises in institutional practice
Pernus, S.

Citation for published version (APA):

General rights
It is not permitted to download or to forward/distribute the text or part of it without the consent of the author(s) and/or copyright holder(s), other than for strictly personal, individual use, unless the work is under an open content license (like Creative Commons).

Disclaimer/Complaints regulations
If you believe that digital publication of certain material infringes any of your rights or (privacy) interests, please let the Library know, stating your reasons. In case of a legitimate complaint, the Library will make the material inaccessible and/or remove it from the website. Please Ask the Library: http://uba.uva.nl/en/contact, or a letter to: Library of the University of Amsterdam, Secretariat, Singel 425, 1012 WP Amsterdam, The Netherlands. You will be contacted as soon as possible.
The present chapter delves into participation in the strategic management of agencies. Managerial responsibilities concern a range of tasks pertaining to the effective day-to-day operation of agencies, such as planning and budgetary matters. This chapter explores two variations of the involvement of interested parties in managerial tasks. On the one hand, interested parties may be involved in the management boards of agencies directly, as full voting members. On the other hand, interested parties may participate indirectly in strategic management, by means of an advisory group which assists the management board or as observers. It is assumed that direct and indirect forms of managerial participation are intended to accomplish distinct promises. If this is correct, the question becomes what exactly do such promises entail? And, more importantly, are they actually fulfilled? In the pages below, the function and the meaning of each variation will be revealed in the light of the formal and informal arrangements of access and the overall quality of deliberation (i.e. the actual influence of participation).

4.1 Access to Managerial Participation: Direct and Indirect Involvement

The focus of this section is on different ways in which interested parties can access the managerial tasks of the agencies. The analysis of the founding regulations of agencies has revealed that managerial participation can take two distinct forms. First, interested parties may be immediately involved in agencies’ main steering bodies – their management boards, and second, they may interact with the latter indirectly via an advisory board and as observers. At the de jure level, the EMA and the EFSA founding regulations envisage the involvement of representatives of affected interests, or of those who have a background in organisations representing such interests, as full members of their management boards, whereas the EASA founding regulation anticipates the establishment of an advisory body – the EASA Advisory Board – entirely composed of interested parties, which assists the management board of the agency. In addition, the EASA regulation foresees the admission of four members of the Advisory Board as observers to the agency’s management board, without, however, voting rights. It is expected that such variations of managerial participation fulfil different functional roles and, thus convey distinctive promises. By considering the formal mandates and tasks that interested parties are entrusted, the following pages will identify the intended promises of managerial participation and determine whether and how they are fulfilled on the basis of rules and practices pertaining to the key elements of access: composition of participatory forums, selection procedure and representativeness of interests.

1 See Chapter 2, Section 2.2.
2 Respectively, Art. 65(1) of Regulation (EC) No 726/2004, as subsequently amended; Art. 25(1) of Regulation (EC) No 178/2002, as subsequently amended.
4 Ibid. Art. 34(3).
4.1.1 Variation 1: Direct Managerial Participation

A) Management Boards: Formal Mandates and the (Un)usual Composition

Management boards are the integral governing bodies of agencies and pursue a wide variety of tasks pertaining to the smooth and effective functioning of agencies. Their establishment, composition and mandate are elaborated in considerable detail in the founding regulations of agencies. These formal rules reveal several common responsibilities of the management boards of agencies, which include a supervisory role with respect to budgetary and planning matters, determination of strategic plans and future directions, adoption of annual work programmes and reports concerning the activities of agencies, as well as the adoption of rules regarding the internal organisation of agencies.\(^5\) In addition, management boards play an important role in the appointment and dismissal of executive directors (i.e. the heads of the agencies), who are responsible for a day-to-day operation of agencies.\(^6\)

The overall composition of the management board varies from one agency to the next. Normally, however, management boards are composed of representatives from each Member State, as well as, depending on the agency, representatives from the European Commission, the European Parliament, and various interested parties. As it will be demonstrated, the management board of the EMA is in line with this “usual composition”,\(^7\) whereas the EFSA is governed by a management board that comprises independent members who are appointed to act in the interest of the public “without any post being reserved for nationals of any specific Member State.”\(^8\) We will now examine more closely the composition of the EMA and the EFSA management boards, which admit representatives of the interests concerned, or those who have a background in organisations representing such interests, as members.

According to the EMA founding regulation, the EMA management board includes four civil society representatives - two representatives of patient and consumer organisations, and one representative of each doctor and veterinarian organisations - as full voting members of the board.\(^9\) For the rest, the EMA management board is primarily composed of Member States’ representatives: as many as 28, out of a total number of 36 board members, represent Member States.\(^10\) In addition, two representatives from the European Commission and two representatives from the European Parliament are also members of the board.\(^11\) Given the prevalence of the

---

6 See for example, Art. 26(1) of Regulation (EC) No 178/2002, as subsequently amended; Art. 64(1) of Regulation (EC) No 726/2004, as subsequently amended; and Art. 39(1) of Regulation (EC) No 216/2008, as subsequently amended.
7 The management boards of the EASA and the EBA also follow this usual composition; however, they do not include interested parties (directly) as members.
9 Art. 65(1) of Regulation (EC) No 726/2004, as subsequently amended.
10 Ibid.
11 Ibid.
Member States’ representatives, the EMA management board could well be compared to a board of directors of a company, where Member States are the main stakeholders.

The composition of the EFSA management board is, however, notably different. This agency’s board consists of 15 independent voting members, including a Commission representative, of which four members need to have “their background in organisations representing consumers and other interests in the food chain.”\(^\text{12}\) A close inspection of the EU policy documents guiding the establishment of the EFSA reveals the legislator’s ambition to establish an organisational structure that would assure independence from any external pressures.\(^\text{13}\) Such a unique composition of the EFSA management board, which excludes Member States’ representatives, should be understood “against the backdrop of the crisis of confidence in Community regulation, its scientific advice, and the food industry in general, calling for dramatically enhancing credibility and removing any inch of influence whatsoever.”\(^\text{14}\)

**B) Promises: Navigating Between Interest Representation and Interest Observance**

Having addressed the mandates and the composition of the EMA and the EFSA management boards, the following questions become relevant in order to identify the promises of this form of participation: What is the role assigned to interest representatives or to those whose background is in organisations representing concerned interests in the management board? In what capacity do they participate in the management board and what is their relevance? How, if at all, are they different from any other member of the board? Can they even be considered as interested parties *sensu stricto*?

At the *de jure* level, the examination of the EMA and the EFSA founding regulations reveals that in both cases all members of the management board need to be appointed “in such a way as to guarantee the highest level of specialist qualifications, a broad spectrum of relevant expertise and the broadest possible geographic spread within the European Union.”\(^\text{15}\) Besides these, there are no particular provisions concerning eligibility of interest representatives in the EMA management board and of those having background in organisations representing concerned interests in the EFSA board, or any assessment criteria for their appointment. Nevertheless, the EU institutions have developed informal criteria in this regard. As it will be shown below, the selection of interest representatives and of those having background in relevant organisations is entirely in the hands of the EU institutions.

---

\(^\text{12}\) Art. 25(1) of Regulation (EC) No 178/2002, as subsequently amended.


\(^\text{15}\) Art. 65(1) of Regulation (EC) No 726/2004, as subsequently amended; See also, Art. 25(1) of Regulation (EC) No 178/2002, as subsequently amended.
What then distinguishes interest representatives from other members of the management boards of agencies, such as Member States’ representatives? According to past public calls for expression of interest to become an interest representative in the EMA management board, issued by the Commission, the applications for membership need to be assessed against the following criteria. In addition to the above-mentioned formal criteria, the assessment is based on “whether individuals represent patients’, doctors’ or veterinarians’ organisations at a European level”, and on their “ability and experience in representing organisations, and characteristics of the organisations represented.” From this, it can be inferred that representativeness of societal interests affected by the EMA operation, rather than expertise, has clearly been preferred as the main criterion for the appointment of such members to the management board. The empirical evidence (i.e. interview data), however, reveals that interest representatives participate in the EMA management board in their personal capacity and independently, and once appointed they generally do not affiliate with their background organisations in the matters concerning the work of the management board. They are not, in particular, subject to any mandate by, or reporting obligation to, their background organisation. As such, they consider themselves independent members of the board who, when applicable (i.e. in the matters that immediately concern the interests represented), represent “broader” societal interests but never their particular background organisation (Respondent #3, #6, #17, #22). For example, the individuals representing patients’ organisations in the management board represent the interests of patients per se and not the interests of their background organisations (e.g. the European AIDS Treatment Group or International Diabetes Federation European Region). Arguably, the reason for this is the EMA’s strict conflict of interest policy which applies to all members of the management board, including interest representatives. It is assumed that it is easier to “control” the activities (i.e. possible affiliation with the pharmaceutical industry) of an individual participant than those of a background organisation, hence the emphasis on participation in a personal capacity.

Following these considerations, the meaning (i.e. the intended promises) of the participation of interested parties in the EMA management board needs to be considered against the role of the management board as a political guardian of the agency. The representatives of societal interests (patients, consumers, doctors and veterinarians) are admitted to the EMA management board as full members with voting rights, which means that they are given direct access to the full range of the above-mentioned managerial tasks and responsibilities, like any other member of the board. Second, to the extent that they indeed voice the concerns of the interests represented, the presence of interest representatives may be assumed to contribute to more informed outcomes of the EMA management board. Taking into account that interest representatives will possess specific experience and understanding of the societal interests and concerns, their involvement

17 This will be in more detail explained in Section 4.2.
18 According to the EMA policy, the members of the management board shall “have no interests in the pharmaceutical industry which could affect their impartiality.” Any potential funding received from a pharmaceutical company by an organisation/institution (including patients’, consumers’ or healthcare professionals’ organisations) to which a member of the EMA management board belongs constitutes an instance of “indirect interest”. See, European Medicines Agency (2015b), ‘European Medicines Agency Policy on the Handling of Competing Interests of Management Board Members’, EMA/MB/715362/2015, 17.12.2015, pp. 3 and 6.
19 See also, Chapter 1, Section 1.4.
may broaden the spectrum of information available to the board when making decisions. In the same sense, the involvement of interest representatives can be considered as means of ensuring inclusiveness of those concerned (i.e. balancing of different, possibly conflicting interests) and enhancing responsiveness of the EMA managerial decisions (i.e. ensuring that outcomes of the management board take into account the societal concerns). Admittedly, inclusiveness and responsiveness will always depend on the range of interests that are considered. Given the small number of interested parties in the EMA management board, it might be that the degree of inclusiveness and responsiveness is rather low. However, considering that the membership in the EMA management board needs to cover a wide and disperse range of interests (not only societal, but also those of the national authorities) and that the views of the representatives of societal interests (as full voting members) have the same weight as those provided by the Member States’ representatives, it can be argued that there is a reasonable relative level of inclusiveness of, and responsiveness to, societal interests. On the whole, it is assumed that the anticipated promises of participation may eventually enhance the effectiveness of the EMA managerial operation.

In the case of the EFSA, the Commission has also established certain additional eligibility criteria for the selection of the members of the management board. Previous calls for the expression of interest to become a member of the EFSA management board display that all candidates, including those whose background is in organisations representing consumers and other interests in the food chain, need to demonstrate several qualifications to be eligible for the position. For example, all candidates need to show that they have at least 15 years of experience (of which at least five years at a senior level) in one or more of the following five areas of competence: (i) provision of independent scientific advice and scientific and technical support for the preparation of EU legislation and policies pertaining to food and feed safety; (ii) management and public administration; (iii) development of policies ensuring integrity, independence, transparency, ethical practices and high scientific quality advice while maintaining reliability with stakeholders; (iv) effective communication and information to the public on scientific work; and (v) assurance of coherence between risk assessment, risk management and risk communication. In addition, candidates need to prove that they have at least 5 years of experience gained from work in relation to food and feed safety or animal health, environment protection, plant health and nutrition. If a candidate fulfilling such criteria wishes to be considered as one of the four members having a background in organisations representing consumers or other interests in the food chain, the only additional criterion is an indication of (a current or past) affiliation with such an organisation.

On the basis of this evidence, it can be observed that the core criterion for the selection of the EFSA management board members is, in fact, their competence and collective expertise, and not their representativeness of the interests affected in the food chain. This is also highlighted on the EFSA website, which states that the EFSA management board “comprises 15 members who have

20 However, given that participation as an enhanced form of transparency will always depend on how open participation actually is, it can be argued that transparency is not one of the primary promises of this form of participation.

21 See for example, European Commission (2015a), ‘Call for Expressions of Interest for the Position of Member of the Management Board of the European Food Safety Authority’, OJ C 158, 13.5.2015.

22 Ibid.
a wide range of expertise related to the food chain but do not, in any way, represent a government, organisation or sector.”23 This situation is quite different from the one in the EMA management board, where the representatives of the societal interests need to demonstrate that they represent such interests at the EU level and that they are experienced in representing the characteristics of their background organisations. As further corroborated by an EFSA official,

The EFSA management board is composed of individuals representing anyone and anything else but their interests. [...] The fact that four of the management board members need to have a background in consumer organisations or other interest organisations involved in the food chain means that they need to have – at any point in their career - working experience within such organisations: from the consumers, agricultural or trade point of view... Why that? Because it is important that the board also builds on the experience of those who have worked in those realities, who can highlight certain issues or certain dynamics [...] but always bearing in mind that this experience is only part of their background and not an interest they represent. (Respondent #24)

It is clear from the above that the involvement of the four individuals who have a background in organisations representing concerned interests in the EFSA management board is not aimed at ensuring the participation of interested parties sensu strictu. There is, in particular, no reference requiring that such members are appointed to represent the interests of different groups affected by the EFSA mission (unlike the EMA). Whereas such an involvement conveys the general idea of instrumental participation (i.e. collaboration of those who can provide views from different angles and backgrounds), it is, however, not aimed at representing any particular interest, sector or organisation concerned with the EFSA managerially operation. The “vital” missing link is a justification of their representativeness of the affected or concerned interests (e.g. at the EU level) and an indication of the quality of such representation (e.g. experience in representing the characteristics of their background organisations, such as in the case of the EMA). In other words, this means that the participants in the EFSA management board whose background is in organisations representing concerned interests do not fall within the scope of “interested parties” in the sense of this research.24 Following these considerations, it is understood that the composition of the EFSA management board is primarily not directed at ensuring a better involvement of affected societal or economic interests25 and, as a consequence, the EFSA board cannot be regarded a “participatory forum” properly speaking. All this contradicts the implications in the academic literature that the EFSA involves interest representatives or representatives of interest organisations as members of the management board.26 Given that “participation” in the EFSA management board does not immediately relate to “interested parties” (including interest

---

24 See Chapter 1, Section 1.4.
25 See Chapter 1, Section 1.3.
C) Selection of Members: Preserving Agency’s Independence

The selection of interested parties as members of the EMA management board is a responsibility of the EU institutions. At the de jure level, the analysis of the EMA founding regulation reveals that civil society representatives (i.e. representatives of patients’, doctors’ and veterinarians’ organisations) in the EMA management board are appointed on the basis of a competitive process managed by the Commission. According to the rules, the four interest representatives are “appointed by the Council in consultation with the European Parliament on the basis of a list drawn by the Commission which includes appreciably more names than there are posts to be filled.” The selection procedure starts with a public call for the expression of interest launched by the Commission. Based on the applications received within the deadline set in the public call, the Commission prepares a short-list of candidates, which, together with all relevant accompanying documents (e.g. CVs and declarations of interests), is then submitted to the European Parliament for consultation. As soon as possible, but no longer than three months after the notification, the European Parliament may present its views to the Council, which then appoints interest representatives to the EMA management board. The term of office of such members is three years and may be renewed.

Regarding the selection procedure, the choice of those who are considered representative of the concerned interests (i.e. patients and consumers, doctors, and veterinarians) in the EMA management board is entirely in the hands of the EU institutions and not the agency. In other words, the selection of interest representatives is under the immediate oversight of the institutions that have formally envisaged this form of participation in the EMA. One may argue that such a method of appointment is indispensable for preventing the risk of capture and ensuring the independence and the effectiveness of the agency. As the management board has powers of political control over the EMA operation, it is only logical that it is not the agency itself that appoints those who will control it. Moreover, in terms of design, this selection process appears to be capable of promoting representation of the relevant interests. Having identified the ground rules, it is also relevant to inquire how the selection procedure works in practice.

---

27 See Chapter 1, Section 1.4.
28 See Chapters 1 and 2.
29 This method of selection applies only to the appointment of the four interest representatives in the EMA management board. The representatives of the Member States, the Commission and the European Parliament in the EMA management board are appointed directly by a given Member State or the Institution concerned. See Art. 65 of Regulation (EC) No 726/2004, as subsequently amended.
30 Art. 65(1) of Regulation (EC) No 726/2004, as subsequently amended.
31 See for example, European Commission (2011).
32 Art. 65(1) of Regulation (EC) No 726/2004, as subsequently amended.
33 Ibid. Art. 65(4).
On the basis of the Council decisions appointing interest representatives as members to the EMA management board, it can be affirmed that all the prescribed steps of the selection procedure are indeed followed: the Commission prepares a list of candidates, the European Parliament is consulted and the Council considers the views expressed by the Parliament when adopting its final decision. However, the empirical evidence reveals one much-cited aspect of the selection of interest representatives in the EMA management board, which can negatively affect the fulfilment of the identified promises of direct managerial participation. This negative aspect concerns the delay in the selection of the members representing societal interests in the EMA management board. As it will be shown, this was a one-time occurrence; nevertheless, it is illustrative, on the one hand, of the struggle of EU institutions to preserve agency independence and avoid risks of capture and on the other hand, of the negative consequences that untimely appointments may have on the “reputation” of the EU institutions and an agency (i.e. the manner in which the Institutions and an agency are perceived by interested parties).

A close inspection of the above-mentioned Council decisions reveals that in 2011 (the most recent renewal of the membership of interest representatives), the appointment of the four civil society representatives to the EMA management board had been delayed for almost a year. The three year term of the previous members was due to expire on 4 March 2012. Interestingly, the Commission started the selection procedure on time (30 September 2011), and the call for the expression of interest stated that application should be submitted no later than 1 December 2011, which should had provided more than enough time to ensure the continuity of the appointments. However, the Council decision reveals that the Commission submitted its short-list of candidates only on 8 August 2012, which is almost half a year after the end of the term of the previous civil society representatives’ appointments, and the final decision was reached as late as 20 December 2012. According to the respondents, the main reason for the delay in the appointments was the EMA’s very strict policy regarding conflicts of interest (Respondent #14, #17, #22). In the words of one respondent,

The Commission hesitated as to which names to put forward; they did not know what to do. There are unclarities because they have to select representatives [of patients’ and consumers’ organisations, doctors’ organisations and veterinarians’ organisations], but once these people are appointed, they participate in their personal capacity, therefore their independence [from background organisations] and prevention of conflicts [of interest] needs to be ensured. (Respondent #14)

Whereas the pertinence of ensuring agency independence cannot be denied, the respondents from interested parties felt that the delays were not sufficiently justified and considered them “a huge disregard for the interest representatives” (Respondent #6), “an insult” and a manifestation of “how little we matter” to the EU institutions (Respondent #14). The issue was further exacerbated by the fact that in the meantime, the management board had difficulties reaching decisions. As explained by one of the EMA management board members,

Decisions of the management board are adopted by a two-thirds majority [of its members]. And with the absence of the two patients’, one doctors’ and one veterinarians’ representative, it started to be quite difficult to have a majority [in the board]. So also the agency was interested to have this process settled as fast as possible. (Respondent #22)

What is at stake here is, on the one hand, the opportunity of interested parties to access the EMA management board activities and, on the other hand, the operability of the management board as such. In other words, any delays in appointment can have a grave impact on the discharge of the management board’s tasks, on the execution of the legally entrusted responsibilities of interest representatives, and on the fulfilment of the identified promises of participation (i.e. more informed managerial decisions, inclusiveness and responsiveness of the EMA operation). Thus, the management board’s power of political control over the EMA (especially due to possible difficulties in regard to decision-making) may be severely hampered. Moreover, delays in appointment may negatively affect the credibility of the agency from the perspective of interested parties. What is worrisome is that responsibility for this failure lies with the EU institutions which established the agency and this form of participation in the first place. As there are no evident deficits in the formal design of the appointment procedure (there are only deficits in regard to its execution), it is the responsibility of the EU institutions to respect the rules in place and ensure effective, credible and continuous operation of the EMA management board in the future.

---

38 The decisions of the board need to be adopted by a two-thirds majority of its members. However, according to the Rules of Procedure of the EMA management board, voting takes place only in situations where there is absence of obvious consensus. If this occurs, the chair of the group asks the members whether they wish to vote following a closure of a debate. Such a vote is open and meeting minutes indicate the members who voted in favour, against and who abstained. See, Art. 65(6) of Regulation (EC) No 726/2004, as subsequently amended; European Medicines Agency (2014a), ‘Rules of Procedure of the Management Board’, EMA/MB/115339/2004/en/Rev.5, 13.2.2014, Art. 6.
4.1.2 Variation 2: Indirect Managerial Participation

A) Establishment, Mandates and Promises

Thus far, we addressed only one “variation” of managerial participation, namely direct involvement of interested parties in the management boards of agencies. The second variation of managerial participation, which entails the involvement of interested parties in the managerial tasks of the EASA via an advisory board which assists the management board and as observers, is notably different in the sense that interested parties are not granted immediate access as full voting members of the management board. It is expected that this form of managerial participation is qualitatively different from the direct one and is intended to accomplish distinct promises. This second – indirect – aspect of the involvement of interested parties in the strategic management of the agencies will be emphasised in due course.

In the case of the EASA, the founding regulation anticipates that the agency’s management board establishes an advisory body – the EASA Advisory Board, entirely composed of interested parties from different sectors of civil aviation, which must be consulted prior to the adoption of the EASA work programme, the establishment of procedures for the development of opinions, certification specification, guidance material and individual decisions (i.e. the EASA rulemaking procedure), and with respect to the agency’s budget, fees and charges.\(^{39}\) In addition, the EASA management board may consult the Advisory Board independently with regard to any other of its tasks.\(^ {40}\) The views of the Advisory Board, however, are not binding on the EASA management board.\(^ {41}\) The interaction with the Advisory Board is further specified in the Rules of Procedure of the EASA management board. These rules establish, in particular, that whenever the Advisory Board needs to be consulted, the management board must notify the Advisory Board about the matter to be discussed and give it an opportunity to express its opinion.\(^ {42}\) When the Advisory Board provides an opinion, the management board needs to put the subject on its agenda at the earliest possibility and respond to the views presented.\(^ {43}\)

The EASA Advisory Board (at the time of its establishment named the “Advisory Body of Interested Parties”) was set up in 2002 by a management board decision.\(^ {44}\) According to this decision, “persons and organisations subject to the rules elaborated, or the powers exercised by the [EASA], shall be entitled to present their views on its functioning, efficiency and achievements and so assist the [m]anagement [b]oard in exercising its control.”\(^ {45}\) Despite the clear, formal mandate of the EASA Advisory Board, the role carried out by this participatory forum was

\(^{39}\) Art. 33(4) of Regulation (EC) No 216/2008, as subsequently amended.
\(^{40}\) Ibid.
\(^{41}\) Ibid.
\(^{43}\) Ibid. Art. 14(3).
\(^{45}\) Ibid.
initially rather vague in practice. The empirical evidence shows that when the Advisory Board was first created, neither the EASA management board nor the Advisory Board itself knew how they should interact. Respondents from the EASA Advisory Board reported that the group had long struggled for a meaningful involvement and felt that this had a negative effect on their actual access to the EASA managerial tasks. In fact, it was revealed that it is only since 2010 (eight years after the establishment!) that the Advisory Board has found its feet and become a fully-fledged advisory body of the EASA management board (Respondents #4, #8, #12). As recounted by an EASA Advisory Board member,

> When we started, [the Advisory Board] did not have any specific purpose, no agenda, and its members were meeting just for the sake of it. Most of the time [the Advisory Board] discussed different topics in very general terms. But such meetings were completely useless – they were time consuming and a lot of money was spent on travelling. So there was this possibility to participate in the [EASA founding] regulation and the management board set up [the Advisory Board], but that did not mean anything. You need to be organised and focused, if you want to be meaningfully involved. (Respondent #8)

This indicates that even where there is a formal opportunity for a group of interested parties to access (a part of) an agency’s activities, there is a risk that such participation remains nothing more than a “feel-good slogan” for a wider audience, if the participants do not understand their role and properly organise themselves in the group. As reported, the situation has since improved. In fact, the EASA Advisory Board members have acted proactively and have organised their operation by adopting their own rules of procedure, which, inter alia, concern the agenda setting and the working arrangements of the Advisory Board. The adoption of such internal EASA Advisory Board rules resulted in a more engaged and effective participatory group which now has an actual chance to live up to its full potential in terms of its mandate (Respondents #4, #8, #12).

The question that arises, then, is why indirect managerial participation by means of an advisory board matters. What promises of participation does it intend to fulfil? Considering the rules regarding the creation and the mandate of the EASA Advisory Board (i.e. the EASA founding regulation and the EASA Advisory Board Rules of Procedure), the primary function of this advisory body is to assist the agency with regard to its managerial tasks. This form of participation, thus, can be understood as means of ensuring interaction with interested parties relevant to the EASA mission. First, the Advisory Board provides the views of the civil aviation organisations concerned, which may increase the range of information available to the EASA management board. Second, given that the EASA Advisory Board needs to be consulted with regard to the management board’s various planning and budgetary matters (e.g. the agency’s work programme, establishment of various procedures, budget, fees and charges) and that the management board needs to respond to the input received, it can be argued that this enhances the responsiveness of the agency’s managerial decisions (in the sense that it allows the managerial decisions to be more

---

46 In the sense that the agency signals to the wider audience that (within the agency) a dedicated group of interest representatives is dealing with stakeholder concerns when in fact this might not be the case.

in line with the needs of the regulated sectors of civil aviation). Third, and related, considering that the EASA Advisory Board comprises various interested parties with different backgrounds (i.e. different shades of opinions), it is understood that this form of managerial participation ensures a certain level of inclusiveness (i.e. balancing of different, possibly conflicting views). However, contrary to the direct involvement of interested parties in the EMA management board, which can immediately influence managerial decisions by means of voting rights (and may thus help exercise political control), the opinions of the EASA Advisory Board are not binding on the EASA management board. Therefore, interest representation in this case cannot be assumed to provide a (separate) source of political control, additional to that of the management board; nevertheless, in a sense, the EASA Advisory Board may carry out a function which is ancillary and “supporting” to that of the management board, especially considering the range of views (i.e. relevant information and potential concerns) that this participatory group might provide.

Additionally, the involvement of the EASA Advisory Board in the managerial tasks of the agency was further boosted in 2008, with the adoption of a new EASA founding regulation 216/2008, repealing regulation 1592/2002. The EASA Advisory Board was given a formal mandate to appoint four of its members to participate as observers to the management board in order to represent, as broadly as possible, different views of the Advisory Board.\(^{48}\) The EASA founding regulation is clear with regard to the promise of participation regarding the Advisory Board’s observers to the management board: this form of participation serves the purpose of transparency of the EASA operation.\(^{49}\) Indeed, the Advisory Board representatives (observers) are given immediate access to the management board meetings; they can observe a wide range of the EASA managerial tasks, and may flag any issue that is of concern to them. In fact, “they can participate in the discussions of the EASA management board” (Respondent #2). However, compared to the immediate involvement of interested parties in the EMA management board discussed above, the EASA Advisory Board observers do not have voting rights and can thus - by virtue of their input - only indirectly influence the management board’s activities.

There are further limits to such participation. In the words of an EASA Advisory Board member, the observers represent the Advisory Board [in the management board], and they can speak on our behalf. But if sensitive issues are being discussed, the Advisory Board observers need to leave the room. (Respondent #8)

Indeed, the minutes of the EASA Advisory Board meetings confirm that the observers are denied access to certain highly delicate aspects of the EASA management board’s operation. Among such “closed session” issues are the election of a chair and vice-chairs of the management board and the appointment of directors of the EASA’s directorates.\(^{50}\) This means that, compared to interested representatives on the EMA management board, the EASA Advisory Board observers are not granted access to the full range of the agency’s managerial tasks. On the whole, it is

\(^{48}\) Art. 34(3) of Regulation (EC) No 216/2008, as subsequently amended.
\(^{49}\) Ibid. Para. 24 of the Preamble.
\(^{50}\) Minutes of the EASA Advisory Board meetings, on file with author.
assumed that in this instance the risks (e.g. conflict of interests and risk of capture) of directly and fully involving interested parties (covering different sectors of civil aviation, including the industry, which the EASA regulates) in the managerial tasks of the EASA, would exceed the benefits. Thus, it can be argued that such arrangements are necessary to preserve the agency’s independence. Nevertheless, the admission of the Advisory Board’s observers to the management board can be understood as “a logical consequence of the fact that EASA’s role is to serve the [aviation] industry which is paying the largest part of the EASA’s budget via fees and charges.”51 Thus, access to (a part of) the management board’s activities as an observer provides, arguably, a first-hand insight (i.e. transparency) into how the EASA spends “their” money, as well as an opportunity to keep track of the EASA’s strategic developments and plans. In this sense, it can be argued that this form of participation comes very close to political control.

B) Composition and Appointment:
Two Dimensions of Ensuring Representativeness

EASA Advisory Board

There are no legal provisions regarding the composition of the EASA Advisory Board and the selection of the interests represented therein. In the absence of a legal determination to this effect, it is the EASA management board that decides which interests (i.e. sectors of civil aviation) are to be represented in the Advisory Board. This situation could be problematic with regard to advancing the identified promises of participation, particularly the inclusiveness of different interests and the responsiveness of the EASA managerial operation, because the agency could be biased as to what interests are allowed access. However, the EASA management board decision that establishes the Advisory Board reveals that the management board strives to ensure a comprehensive membership, which includes the full range of interests affected by the EASA operation.52 Initially, the Advisory Board comprised 21 members, representing the following sectors covered by the EASA founding regulation: aviation personnel (5 members), commercial operators (5 members), the manufacture and design industry (5 members), general/non-commercial aviation operators (3 members), air sports (1 member), the maintenance industry (1 member) and the training industry (1 member).53 The composition of the Advisory Board is not limited to a maximum number of members. In fact, the structure of the group has been reviewed over the years to take into account the growth of the EASA’s remit.54 As of 2014, the EASA Advisory Board comprises

---

54 From the initial responsibility for the airworthiness and environmental certification of aeronautical products, the operation of the EASA has expanded to further sectors, such as air operations, pilot licensing, air traffic management and air navigation services. See for the initial responsibility, Regulation (EC) No 1592/2002.
a total of 25 members: in addition to members representing the sectors listed above, the EASA Advisory Board now also includes representatives of airports (1 member), air traffic control (1 member), of the International Federation of Air Traffic Controllers (IFTACA), and an additional representative of the commercial operators. Thus, it can be argued that the EASA includes a wide and varied range of interests (i.e. sectors of civil aviation) affected by its mission.

The manner in which the members of the EASA Advisory Board are appointed gives us further insights into the representation of different interests. It indicates, in particular, whether everyone who matters for the fulfilment of the primary promises of indirect managerial participation (i.e. more informed managerial outcomes, inclusiveness and responsiveness) is given an opportunity to be included. Again, it is the EASA – the creator of this participatory group – that determines the appointment of the members of the Advisory Board. This situation might be suboptimal for similar reasons to those stated above. However, the agency has proved to be comprehensive in terms of the Advisory Board membership, which could be interpreted as a sign of its commitment to delivering the identified promises of participation. According to the EASA management board decision establishing the Advisory Board, the appointment procedure proceeds as follows. Associations representing the sectors of civil aviation noted above are invited to nominate their members “with a view to ensure a fair and exhaustive representation of all persons and organisations, including small and medium size companies subject to the EASA regulation and its implementing rules.” This effectively means that any organisation from the pool of organisations covering different sectors of civil aviation affected by the EASA operation is eligible to apply for membership of the Advisory Board. Nominations for membership and any changes thereof need to be notified to the EASA management board. If the management board considers that nominations are not sufficiently representative of a given sector, it may object. In this case, the concerned organisations may provide new nominations for the sectors concerned. This can be perceived as an instance of ensuring that all affected sectors of civil aviation are properly represented in the EASA Advisory Board. Each organisation that is formally admitted is represented by an individual who has “a personal membership” in the EASA Advisory Board.

In terms of representativeness, the empirical evidence shows that the management board does not tend to limit the access of interested parties from the various sectors of civil aviation to the EASA Advisory Board. As explained by one member of the EASA Advisory Board,

55 As of 2014, the EASA Advisory Board comprises representatives of the following organisations: aviation personnel – Aircraft Engineers International (AEI), European Cockpit Association (ECA), European Transport Workers Federation (ETF), Federation of Transport Trade Unions in Bulgaria (FTTUB); air sports – Europe Air Sports; general/non-commercial aviation operators – International Aircraft Owners and Pilots Associations (IAOPA), European Business Aviation Association (EBAA), European Council of General Aviation Support (ECOGAS); maintenance industry – European Independent Maintenance Group (EIMG); manufacturers – Airbus, Dassault Aviation, Rolls Royce PLC, Alenia Aeronautica, Agusta Westland; commercial operators – Association of European Airlines (AEA), European Helicopter Association (EHA), European Council of General Aviation Support (ECOGAS); training industry – Lufthansa Flight Training GmbH; airports – Airports Council International (ACI); air traffic control – Civil Air Navigation Services Organisation (CANSO); and International Federation of Air Traffic Controllers (IFTACA). See EASA website, <https://easa.europa.eu/system/files/dfu/List%20of%20EAB%20Members.pdf>.
57 Ibid.
58 Ibid.
If there was an organisation that is currently not included in the group and would express an interest in becoming a member [...], what they would have to do is write a letter to the Advisory Board which then discusses this and then they can put it forward to the management board and they formally accept [the request for membership]. It is a formalised acceptance procedure, but in fact it is only a rubber stamping exercise on the management board’s part, unless they think it really is not a good idea [to admit an organisation as a member of the Advisory Board]. (Respondent #18)

On the whole, the system regarding the access of interested parties to the managerial tasks of the EASA seems to be contributing to the fulfilment of the identified promises of participation. First of all, the EASA management board ensures a wide coverage of stakeholder interests in the Advisory Board, and all sectors of civil aviation that are affected by the EASA operation are indeed included in the group. Additionally, relying on the empirical evidence available, there is nothing to suggest the agency’s disrespect for the formal (self-imposed) rules guiding the establishment of the Advisory Board, the selection of its members and the representativeness of interests (sectors) affected. In terms of the promises of participation it can be argued that ensuring access of a wide variety of interests to the EASA managerial tasks and their representativeness foster the agency’s opportunity to live up to the primary promises of this form of participation: improved quality of the EASA managerial outcomes, inclusiveness and enhanced responsiveness of the agency’s operation.

Observes to the EASA Management Board

Having examined the selection of the members of the EASA Advisory Board, the manner of appointment of the four Advisory Board’s observers to the management board provides further indications of the representation of different interests in the managerial tasks of the EASA. It is understood that the observers will attend the meetings of the EASA management board, represent and communicate the views (concerns) of the Advisory Board and report back to the participatory group, which together increases transparency and monitoring of the managerial operation of the agency.

De jure, the nomination of such observers is in the hands of the Advisory Board itself.60 According to the Advisory Board’s Rules of Procedure, normally the chairperson, the vice-chairperson, and the executive secretary of the Advisory Board will be nominated as observers to the EASA management board for a period of 30 months to express different views represented in the advisory group.61 Interestingly, the EASA management board’s composition, published on the EASA website, reveals a different story. Only the chairperson and the vice-chair of the Advisory Board are designated by name as observers to the management board.62 Relying on the empirical data, reality indeed diverges from the formal rules (i.e. the EASA founding regulation and the Advisory Board’s Rules of Procedure). As explained by an EASA Advisory Board member,

60 Art. 34(3) of Regulation (EC) No 216/2008, as subsequently amended.
We decide in Advisory Board meetings, which are taking place prior to the management board meetings, who will represent us as observers. On some subjects that are of your interest you can say, I definitely want to be one of the observers. So there is a possibility for every Advisory Board member to potentially participate in a management board meeting as an observer. (Respondent #4)

Arguably, this practice seems to be better suited to the EASA Advisory Board’s members, since it does not limit participation as observers to specific members (and interests) of the Advisory Board and to a certain term of office, but it gives every member an opportunity to participate in the management board if an issue is being discussed that is of their particular interest or concern. This situation can be considered as beneficial in terms of furthering the promises of this form of participation (in particular inclusiveness, transparency and monitoring). In other words, one may assume that this practice contributes to a broader and more accurate representation in the management board of the different interests incorporated in the EASA Advisory Board.

4.2. QUALITY OF DELIBERATION: MEANINGFUL INVOLVEMENT?

The above considerations shed light on two variations of access (direct and indirect) to the managerial tasks of agencies and also identified why, in each case, managerial participation is relevant. However, the mere opportunity or a right to access a participatory forum can in no way be understood as meaningful participation in the sense of fulfilling the promises of participation. Indeed, the participation of interested parties is characterised by a further, more dynamic dimension: the overall quality of deliberation (i.e. the actual influence of participation in regard to the intended promises). By reference to three interrelated and interdependent facets of the quality of deliberation, namely access to timely and adequate information, debate/commenting and recognition of the input of interested parties, the following pages will reveal whether and how the identified promises of both variations of managerial participation – the direct and indirect - are actually accomplished.

4.2.1 Access to Information:
Type of Documents and Participants’ Insights

Provision of adequate and timely information is an indispensable facet of the overall quality of deliberation and a necessary precondition for the fulfilment of the envisaged promises of managerial participation. The general requirement in terms of information is that the respective agencies provide particular documents pertaining to the execution of the managerial tasks that the EMA management board and the EASA Advisory Board are entrusted with. According to

---

63 See Chapter 2, Sections 2.3.2 and 2.4.
the EMA and the EASA founding regulations, such documents need to include, for example, drafts of the annual work programme, of the annual report covering the activities of the agencies in the previous year, and of the estimates of revenue and expenditure (budgetary matters) of the agency.64 The respondents from both participatory groups confirmed that such informing obligations are *de facto* fulfilled.

Furthermore, regarding additional information, the minutes of the EMA management board meetings reveal that at each meeting, the agency’s executive director presents so called highlights, which may include presentations on the EMA’s recent activities, new and planned policies, and pending developments. Also, additional information may entail reports from the European Commission to the EMA management board regarding the development of EU legislation and policies in the public health area.65 In the case of the EASA, the minutes of the Advisory Board unveil that additional information provided to the Advisory Board includes presentations and explanations by the executive director of the agency and, occasionally, by the chair of the management board.66 And since four of the Advisory Board members can participate as observers at each of the EASA management board meetings, this means that they will be able to bring the information presented during such meetings (i.e. reports from the agency’s executive director and the agency’s presentations) to the rest of the group. This shows that the information provided to these participatory forums is actually a mix of formally required documents and informal presentations.

The provision of information is, moreover, guided by the internal rules of agencies (i.e. rules of procedure) which determine when the documents need to be submitted to the relevant participatory forums. In the case of the EMA management board, the agenda, accompanied by all relevant documents, needs to be forwarded to the members at least two weeks prior to each meeting.67 However, in extraordinary circumstances, these timelines may be shortened.68 Similarly, the rules of procedure of the EASA Advisory Board provide that “all available documentation (draft agenda, reports, working papers etc.) shall be distributed to the members [...] four weeks before the meetings and will be made available in electronic form when possible and placed on the [EASA Advisory Board] website when available.”69

---

67 European Medicines Agency (2014a), Art. 3(2).
68 Ibid. Art. 5(2).
Table 4.1 Overview of the Promises of Managerial Participation/Type of Information/Deadline

<table>
<thead>
<tr>
<th>Identified Promises of Participation</th>
<th>EMA Management Board (4 representatives of societal interests)</th>
<th>EASA Advisory Board and Observers</th>
</tr>
</thead>
<tbody>
<tr>
<td>- More informed outcomes.</td>
<td>- Increase the range of information available to the EASA.</td>
<td></td>
</tr>
<tr>
<td>- Inclusiveness and responsiveness.</td>
<td>- Inclusiveness and responsiveness.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Transparency and monitoring.</td>
<td></td>
</tr>
<tr>
<td>Information/Documents (Examples)</td>
<td>Draft annual work programme, draft annual report, and draft statement of estimates of revenue and expenditure of the agency.</td>
<td></td>
</tr>
<tr>
<td>Deadlines</td>
<td>2 weeks prior to each meeting.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- May be shortened in urgent cases.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>4 weeks prior to each meeting.</td>
<td></td>
</tr>
</tbody>
</table>

The rules on the provision of information and the established practices guiding the additional informing indicate that the type and the nature of information that the members of the EMA management board and of the EASA Advisory Board are supposed to receive coincides with the managerial tasks of these participatory forums. This means that such agency arrangements, if in fact respected, are likely to further the overall quality of deliberation and contribute to the fulfilment of the promises of managerial participation as identified in the primary observation. However, the promises may only be promoted insofar as the agencies ensure adequate and timely information and allow for a sufficient preparation ahead of the participatory group’s meetings. With a view to ascertaining whether such requirements are actually met, an account of how the provision of information works in practice is given below. In particular, relying on the empirical evidence, it will be established whether the information received is de facto sufficient and timely. At the same time, the participants’ capacity to deal with the information received (i.e. their preparation) will be investigated.

Generally, the respondents from the EMA management board and the EASA Advisory Board felt that they are adequately informed on different issues specified above. As reported by a respondent from the EMA management board, the relevant documents are “intermittently placed on the intranet, so you can immediately scan them. Not only that – also Power Point presentations, prepared by the EMA staff, you can read before [the meetings]” (Respondent #17). In line with this view, the EMA respondents generally felt that the provision of information is timely and that there is more than enough time to prepare for the meetings (Respondent #3, #6, #17, #22).

Moreover, according to the empirical evidence, the representatives of the societal interests in the EMA management board generally felt that they were knowledgeable and experienced enough to deal with the information received and to adequately prepare for the execution of the group’s administrative tasks (Respondent #3, #17, #22). The respondents also remarked that despite acting in their individual capacity, they nevertheless try to ensure that, where applicable, the views of those concerned (i.e. patients, consumers, doctors and veterinarians) are observed. In the words of one respondent from the EMA management board,
I also act as an observer to the Patients’ and Consumers’ Working Party, so I look through the special questions [i.e. concerning the different interests] that I have and ask them for opinion. But not in a way like “I am now talking to you as your representative in the management board and I am collecting your opinions.” [...] Also, I regularly browse through the websites of patients’ organisations and they really have some wonderful information there. (Respondent #17)

Similarly, another member of the EMA management board remarked,

If needed, I would of course contact my background organisation ahead of the meetings to make sure that indeed I was representing the voice of healthcare professionals. I would bring up the general issues in the [background organisation] and discuss them. (Respondent #6)

All in all, it seems that the representatives of the patients’ and consumers’, doctors’, and veterinarians’ organisations in the EMA management board inform themselves about the broader concerns of interested parties and also adequately respond to the information provided by the agency. Therefore, it may be perceived that such practices positively contribute to the fulfilment of the primary promises of this form of participation, especially the promise of more informed managerial outcomes.

On the contrary, the respondents from the EASA Advisory Board have repeatedly complained that they receive information with delays. This situation is problematic, as it can seriously undermine the delivery of the envisaged promises of participation. In particular, untimely presentation of information may affect the participants’ possibility to adequately prepare their input, which in turn might diminish the quality of the factual resources available to the EASA management board, as well as responsiveness of the agency’s managerial affairs. In addition, late information may also hinder transparency and monitoring over the EASA operation. In this connection, a respondent from the EASA Advisory Board protested,

Once every three months\textsuperscript{70} there is a pile of documents. We always ask the EASA for information well in advance, but this time, again, I received fifteen documents, each six to seven hundred pages long, just three days before the meeting. It is impossible to even get a quick read, let alone a good grip of what is being done. We have been complaining for the last ten years that we need documents further in advance. And they [the EASA] say that the documents are not finished. You can say a lot of things to me, but for many documents they already have two or three versions before the final one. And even with [the earlier versions of documents] you can see in which direction certain discussions are going. (Respondent #4)

\textsuperscript{70} The EASA Advisory Board meets four times per year, usually a week ahead of the agency’s management board meetings.
Other respondents from the EASA Advisory Board also referred to delays, explaining that “[the Advisory Board] meets one week before the next management board meeting and we focus on the working papers from the management board. But in reality, these papers never arrive on time, sometimes we receive them just the day before the meeting or the night before, and another part only after our meetings. Why? Because the EASA is focusing on the management board and not on the Advisory Board” (Respondent #8). The matter is additionally complicated if, for organisational reasons, the Advisory Board meets two weeks before the management board, as then the members are “really struggling to get anything from the agency” (Respondent #18).

These empirical findings concerning the EASA Advisory Board give contradictory signals with regard to the intended promises of participation. At first sight, one could claim that, in terms of information, the EASA is more concerned with the operation of the agency’s management board and that it neglects the proper functioning of the Advisory Board - the participatory group that the agency is legally obliged to interact with. What is less evident at first glance is that the consequences of untimely submission of information may be even more far-reaching. As explained by one EASA Advisory Board member,

We are fighting an administrative monster. This is a feeling we have towards the EASA. You cannot grab this monster and keep it in tight grip and say “now you have to listen”. It is like fighting an octopus with eight arms. So that is a problem. And it is frustrating that we receive information very late, but you know what they say: “if you want to keep something a secret, you have to bury it in a mountain.” Because you can sneak in small things, like one page proposal in 1200 pages of documents, hoping that nobody had read them. (Respondent #4)

Are there any changes on the horizon? In this respect a further Advisory Board member quipped,

If you are smart and a good politician, you would probably say “let’s keep it this way, do not change it; because if [the Advisory Board] cannot read it, they cannot influence the process.” (Respondent #12)

This situation is highly problematic for the overall quality of deliberation, especially considering that untimely provision of information would likely negatively affect the ability of the EASA Advisory Board members to prepare for meetings and impair the level and the quality of the debate in the group. Additionally, unlike the EMA management board, where the members participate in their individual capacity, participants might need to consult their background organisations before the meetings in order to represent their views. In this connection, one EASA Advisory Board member reflected,

Mostly I am working based on my own judgements of what I think is the right thing to do. Especially because of the fact that we receive the documents so late, I just try to go through the material which is of high importance for me. [...] Communication with [the background organisation] before the meetings is hardly possible. (Respondent #4)
Untimely information also seems to negatively influence the preparation of the Advisory Board’s observers to the EASA management board. Given the primary purpose of the participation of observers in the management board, this deficiency may decrease transparency and monitoring of the agency’s managerial operation. Also, considering that the observers are invited to present the views of the Advisory Board in the management board meetings, any flaw in the preparation may affect the quality of the input provided. As another Advisory Board respondent explained,

Because the documents come in so late it is sometimes only in the meetings that we are able to read quite fast through some papers, which is absolutely wrong in my view. And then we try to do something with it, so that the poor people [the Advisory Board’s observers to the management board] will have some general idea as to how to present the interests of the group. (Respondent #12)

To this extent, it appears that the informing practices of the EASA may diminish the overall quality of deliberation and the subsequent fulfilment of the primary promises of indirect managerial participation. The EASA Advisory Board is first and foremost intended to provide advice and increase the range of quality information available to the agency’s management board. However, due to the EASA untimely informing practices, the participants’ possibility to prepare for the execution of their responsibilities may be suboptimal. In addition, this is also problematic in terms of interest representation, as it can lead to situations where the participants will have to rely on their own knowledge instead of representing the immediate interests of their background organisations, to the detriment of their formal obligations. There is no objective reason why the EASA’s delays in the submission of documents should come at the expense of representativeness of different interests and quality input provided by the participants. Given that the formal deadlines for the submission of information are assumed to be adequate for the fulfilment of the primary promises of participation (i.e. more informed managerial outcomes, inclusiveness and responsiveness and monitoring), this deficiency could only be mended if the EASA’s respected their own self-imposed rules.

### 4.2.2 Debating and Commenting: Specifics and Deficits of Engagement

Immediate interaction between the agencies and interested parties occurs in the participatory groups’ meetings. Thus, to determine the overall quality of deliberation, one also needs to look beyond the provision of information and examine particular elements of debate that might affect managerial participation.71 This section attempts to emphasise two particular issues. First, it seeks to show how interested parties in the EMA management board engage in debate in order to represent societal interests. On the one hand, the role of such members is expected to be no different from the role of any other member of the management board (i.e. of the Member States’ representatives): it concerns the execution of the board’s managerial tasks. On the other hand, however, it is assumed that the participation of interested parties ensures the provision of quality

---

71 See Chapter 2, Sections 2.3.2 and 2.4.
information pertaining to the needs and concerns of patients, consumers, doctors and veterinarians and furthers the EMA responsiveness towards such interests. The inquiry into the latter aspect of the participation of interested parties in the EMA management board is indispensable for determining the extent to which the primary promises of direct managerial participation are actually furthered. Second, it intends to pinpoint possible problematic aspects and good practices of the engagement of interested parties in the discussions of the EASA Advisory Board and their impact on the overall quality of deliberation and the envisaged promises.

A) Representation of Societal interests in the EMA Management Board Debates

In terms of participation, the EMA management board is rather specific in the sense that it mainly consists of the representatives of Member States and includes only four representatives of societal interests (i.e. patients and consumers, doctors, and veterinarians). As observed before, interested parties in the management board, like the rest of its members, are primarily concerned with the discharge of managerial tasks; essentially, they do not have a specific function. This was confirmed by one interest representative, who remarked that their role as a member of the EMA management board “is no different to anybody else’s fundamentally. [...] My personal view is that, as a member, my first and my primary responsibility is to make sure that the agency is well governed, and that it has realistic objectives, has a mission and a vision, and a plan to fulfil, and that this all is properly managed” (Respondent #3). This was also confirmed by other interest representatives in the EMA management board (Respondent #6, #17, #22).

But given that such members of the EMA management board are representatives of the interests affected by the agency’s operation, “there are differences by definition. We have a different angle; [in comparison to the Member States’ representatives] we bring the perspective of the society and of patients and consumers to the board” (Respondent #22). However, if we examine the EMA management board as a whole, the majority of its tasks concern the smooth and effective functioning of the agency (e.g. supervision of budgetary and planning matters, determination of strategic plans and future directions, and the appointment and dismissal of the executive director), which do not necessarily require representation of the interests affected. As explained by another interest representative in the EMA management board,

What I try to do with other [interest representatives], when it is appropriate, is to make a contribution on issues where [...] one is striving to say “are you sure how you are involving patients in the determination of this matter?” Or if the agency is setting-up a new procedure, we ask “are patients adequately involved?” I think this is my role. However, I do not think it is my role to constantly stick up my hand and say “patients, patients, patients.” Some issues [in the management board] are not at all about patient involvement; so patient involvement where appropriate. And I try to be realistic about that. (Respondent #3)

But what are the interest representatives effectively doing on behalf of the interests they represent? In this regard, one of the doctors’ representatives claimed that their biggest achievement as a
member of the management board was the formalisation of the doctors’ interaction with the EMA, namely in the form of a Healthcare Professionals’ Working Party.72 “I have been fighting for it ever since I have become a member [of the management board]” (Respondent #6). In addition, according to the same respondent,

If you look at the yearly programmes, you can see that there is [...] more and more emphasis on the relations with the patients and physicians. In the way how the agency looks at its activities and keeps in mind that these parties need to work with what the agency does. And I think it is clear that there is more emphasis on the interaction with interest groups and on the need that they are fully involved in the agency’s work through different channels. And [interest representatives in the management board] have contributed to this change.

Moreover, in the words of one patients’ representative in the EMA management board, “my topic is really the voice of patients. So I make sure that I have good knowledge about different diseases and the urgency for them, and bring this information forward in the discussions. Secondly, it is my goal, and that is not a secret, that the periods for medicines licensing need to shorten. [...] The so-called adaptive licensing is really a concrete goal for me” (Respondent #17). Or as remarked by another patients’ representative,

What I am very much interested in is the interaction of the agency with the society and the media. Indeed, increasing the transparency of the agency operation and making sure that it is better understood by the society. And for all that, we must make an effort that the information is clear and accessible to patients. And that involves a lot of work for the agency. (Respondent #22)

All this corresponds to the functions of the EMA management board and the primary promises of direct managerial participation (i.e. the expected promises of interest representation in the EMA management board). As it emerges from the considerations above, the four representatives of patients’ and consumers’, doctors’, and veterinarians’ organisations, as full members of the board, help exercise political control over agency (which is their main task). Beyond this, participation of interested parties may increase the pool of relevant information available to the EMA management board and may contribute to better and more informed managerial outcomes. Last but not least, to the extent that such participation enhances consideration of the interests concerned, it also favours the responsiveness of the EMA operation. On the whole, it can be argued that the involvement of interested parties at this second stage furthers the overall quality of deliberation and facilitates the accomplishment of the promises of direct managerial participation.

B) Engagement in the EASA Advisory Board Debates

The EASA Advisory Board comprises representatives from different sectors of civil aviation. In terms of debate, members of the group will be more active with regard to any issue that might affect their background organisation and will, in such instances, attempt to bring forward their particular interests. One of the members of the EASA advisory group provided the following explanation,

There are members who are more active than others. Very often this depends on the issues on the agenda. The Advisory Board agenda often has bigger effects on manufacturers and airlines and less of an effect on general aviation. So, as a result, the general aviation representatives give less input” (Respondent #18).

In the same vein, “not every agenda item is to my interest. So I do not take part in discussion about airports and traffic management unless it has a direct influence on what I am doing. So it is usually only five or six members [out of 25] that are actually involved in discussions” (Respondent #4).

Considering that not all matters discussed will equally affect every interested party, this situation cannot be interpreted as detrimental to the fulfilment of the primary promises of this form of participation, in particular the provision of views that may lead to more informed managerial outcomes of the EASA. However, problems could arise if inadequate debate occurs as a consequence of delays in the provision of information to the group by the agency. One member of the EASA Advisory Board complained,

Sometimes you are in a meeting and you just have to discuss and form your own opinion without any backup, and you do it based on your own knowledge and, hopefully, a bit of common sense. [...] In theory we are fully informed, but in practice the documents come in so late [...] which means that it is not very easy for the Advisory Board to form a well-educated opinion on them, because we have to basically do it on the spot. (Respondent #18)

In the same vein, another respondent from the EASA participatory group referred to the following inconveniences for discussions:

If we would have more time to prepare for the Advisory Board meetings and better coordinate our views, the discussions could go further. This means that the advice given to the EASA would have a better impact and would help the EASA make better decisions. But there is too much hurdle now, it is like bulldozing. You are trying to push forward and the mountain in front of you goes bigger and bigger. (Respondent #4)

On the whole, this shows that the quality of discussions may indeed be hampered because of the inadequate preceding step, namely the provision of information. This can lead to situations where the views of participants will need to be formed on the spot and certain issues might be insufficiently debated. Moreover, it can cause inconveniences in terms of interest representation, as the members of the EASA Advisory Board might not be able to coordinate their input with
their background organisations ahead of the meetings and will, therefore, need to act on their best personal knowledge. If the involvement of the representatives of different sectors of civil aviation is in fact grounded in the EASA's need to gather quality information and ensure inclusiveness and responsiveness, then these promises of participation seem to be insufficiently fulfilled.

4.2.3 Input and Recognition: Divide et Impera

The final facet of managerial participation that needs to be examined in order to determine the overall quality of deliberation is the participatory groups’ input and the agencies’ recognition thereof. Do the results of the involvement of interested parties in the EMA management board and the EASA Advisory Board correspond, structurally, to the envisaged promises of participation? Moreover, how do the respective agencies acknowledge and respond to the input provided?

As observed above, the EMA management board approves the essential documents pertaining to the administrative functioning of the agency (e.g. annual work programme, annual report, and budgetary matters). In this respect, the representatives of patients’ and consumers’, doctors’, and veterinarians’ organisations, as full members, contribute to the outcomes in the same way as any other management board member: they can deliberate and vote on any outcomes of the group. In addition, the views of the interest representatives, expressed with regard to any other matter discussed in the board are summarized in the minutes of meetings. In fact, the results of such participation correspond to the identified promises of participation.

In terms of the agency’s recognition, the respondents generally reported that they could often recognise practical manifestations of their contributions (Respondent #3, #6, #17, #22). As noted by one EMA management board respondent, the views of the interest representatives “are certainly heard. Where an opinion [of interest representatives] is a key part of what is being discussed, the rest of the management board reflects faithfully to it” (Respondent #3). In this regard another interest representative in the EMA management board remarked,

Everything that the four [interest representatives] say is always taken very seriously and that helps. At least it gives you enough energy to continue. If you would not be heard, that would be discouraging. (Respondent #6)

The empirical evidence is consistent with the preliminary observations made in regard to the promises of this form of participation. The interest representatives are indeed given an opportunity to fully contribute to the realisation of the EMA administrative tasks. In addition, to the extent that such members voice societal interests, this increases the range of relevant information available to the EMA management board and allows the agency’s operation to be more in tune with societal concerns (e.g. more emphasis on the relations with societal interests, making the agency’s operation more comprehensible). On this basis, it can be argued that this positively influences the effectiveness of the EMA managerial tasks and also promotes the agency’s credibility.

73 See Chapter 2, Sections 2.3.2 and 2.4.
<table>
<thead>
<tr>
<th>Managerial Participation</th>
<th>EMA Management Board (4 representatives of societal interests)</th>
<th>EASA Advisory Board</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>- Annual work programme, annual report, and the budget approved.</td>
<td>- Circulation of the meeting minutes among the members and, where applicable, to the EASA management board.</td>
</tr>
<tr>
<td></td>
<td>- Publication of the meeting minutes on the EMA website.</td>
<td>- Publication of the EASA management board meeting minutes on the EASA website (stating the views of the observers from the Advisory Board).</td>
</tr>
<tr>
<td></td>
<td>- Annual report on the interaction with patients’ and consumers’ organisations.</td>
<td>- Exchange of views with the EASA management board representative and the executive director in the meetings.</td>
</tr>
<tr>
<td></td>
<td>- Exchange of views in the meetings.</td>
<td>- Exchange of views with the management board via observers.</td>
</tr>
</tbody>
</table>

In the case of the EASA Advisory Board, which assists the agency’s management board, the respondents observed that the main route in which they can get their message across is through their observers on the agency’s management board (Respondent #12, #18). We have seen that even though the observers from the Advisory Board do not have voting rights, they can, nevertheless, present their views during the management board meetings. Their interventions are recorded in the EASA management board minutes, however, “the actual uptake of [the Advisory Board’s] comments is marginal” (Respondent #18). Moreover, whenever the EASA management board consults the Advisory Board prior to the adoption of the EASA work programme, establishment of procedures for the development of opinions, certification specifications, guidance material and individual decisions, and adoption of budget,\(^{74}\) the advisory group responds to the management board in writing.\(^{75}\) Such correspondence is sent to the chairperson of the management board and is systematically circulated to all other management board members.\(^{76}\) Also, the views of the EASA Advisory Board are recorded in the minutes of the group’s meetings, which are distributed to the management board.\(^{77}\) All of the EASA Advisory Board respondents confirmed that the group frequently uses these two channels of communication with the management board (Respondent #4, #8, #12, #18). Additionally, the minutes of the Advisory Board meetings reveal that the group exchanges views with the agency’s executive director and the chair of the management board immediately in the meetings.\(^{78}\) The same respondents reported that the EASA reflects upon and responds to the Advisory Board’s input either immediately in the Advisory Board meetings or in the EASA management board meetings (interaction via observers).

As such, the EASA Advisory Board contributions and the recognition thereof correlate with the promises that such participation is intended to fulfil. However, the group’s input could clearly be improved if the EASA would submit the relevant documents to the group in a timelier manner and thus give the participants sufficient time to prepare and discuss their views. In turn, this would enhance the range of quality information available to the agency’s management board. Besides, the respondents were critical of the actual contribution of the group for another reason. As one member of the EASA Advisory Board tellingly observed,

\(^{74}\) Art. 33(4) of Regulation (EC) No 216/2008, as subsequently amended.
\(^{76}\) Ibid.
\(^{77}\) Ibid, p. 8.
\(^{78}\) European Aviation Safety Agency (2011c); European Aviation Safety Agency (2012b).
Everybody in the group has their own concerns and everybody is concentrating on their own business. Personally, I think that for the EASA this is very convenient. Why? Because the operators and the unions [aviation personnel] might have different views on the flight time limitations or the manufacturers would like to simplify certification issues and the operators are victims of that. So if such issues take place, there will never be a unanimous position. So it is like the Romans said: divide et impera. So, if you divide the opinions, you are safe. In my personal opinion, this is a perfect tool for the EASA. Have different groups together and you can be sure that there is nothing coming out of it that will hurt you. And you can go on. (Respondent #8)

Related to this matter, there was also a certain level of dissatisfaction among the respondents regarding the agency’s recognition of the Advisory Board’s contributions. Generally, the respondents felt that their impact on the EASA is rather limited (Respondent #4, #8, #12, #18). However, given the formal mandate of the group, this situation seems inevitable. The EASA Advisory Board was conceived as an inclusive advisory group of interested parties; hence, a limited influence of the group is expected, and the balancing of the participants’ views is bound to happen, especially when the group is requested to present a common position to the agency. This may lead to divisions in the Advisory Board that possibly give the EASA more leeway in “recognising” the participatory groups’ outcomes. As for the actual fulfilment of the intended promises of indirect managerial participation, it may be argued that to the degree that the agency provides (timely and adequate) information to the Advisory Board either directly or via the observers, this form of participation enhances transparency towards those concerned and allows monitoring of the EASA administrative work. For the rest, the EASA Advisory Board cannot be perceived as nothing more than a decent discussion group, aimed at exchanging the views and information among the members and with the agency.

4.3 CONCLUSIONS

This chapter critically analysed two variations of managerial participation, namely the direct and the indirect one. It was shown that depending on whether interested parties are involved in the agency’s management board immediately as full voting members or interact with the management board indirectly via an advisory board and as observers, managerial participation assumes slightly distinctive functional roles.

The empirical study of direct managerial participation in the case of the EMA management board and of indirect involvement via the Advisory Board and as observers in the case of the EASA, revealed that, in both cases, participation primarily intends to serve the purpose of better and more informed managerial outcomes: those most concerned with the operation of the agency (e.g. representatives of societal interests or different sectors of civil aviation) may present their views and, thus, increase the range of information relevant for the discharge of the management boards’ tasks. Indeed, interested parties may possess specific factual knowledge and comprehension of the societal or sector specific concerns (e.g. regarding medicines or aviation safety), and
their views add to the information available to the board when making managerial decisions. In addition, given that in both cases the participants represent particular interests and voice their concerns, it can be argued that direct and indirect participation furthers responsiveness of the agencies’ managerial operation and inclusiveness of different, possibly conflicting views. All this, formally at least, may eventually enhance the effectiveness of the EMA and EASA management. In addition, the primary sources show that participation of interested parties as observers to the EASA management board is intended to fulfil the promise of enhanced transparency and monitoring over the agency’s expenditure. Considering that the EASA is largely funded by fees and charges paid by the aviation industry, monitoring could further the credibility of the EASA with respect to budgetary matters.

Generally, it was confirmed that in terms of access to managerial participation and the overall quality of deliberation the formal arrangements are adequate and correspond with the primary promises. The failures that arise are principally related to the actual application of these arrangements. Such deficiencies constitute risks that the intended promises of managerial participation might not be fully accomplished in practice or could be hindered. In the case of the EMA, the empirical evidence revealed that delays in the appointment of the representatives of societal interests result in the fact that none of the envisaged promises can be fulfilled in a given period because there will be no participation. On one occasion the appointment of new interest representatives was postponed for more than a year due to the EMA’s strict policy concerning the conflict of interests. Whereas such policies are important for ensuring the independence of agencies and avoiding the risk of capture, it may be argued that such issues could be dealt with within the formal timeframes of the selection procedure. Therefore, it is submitted that the delays were not sufficiently justified. In this case, the responsibility for impeding the fulfilment of the promises of managerial participation can be attributed solely to the EU institutions and not the agency. However, what is at stake here is the overall credibility of the EMA managerial operation (i.e. how the agency is perceived to deal with or respond to the concerns of those affected). Given that this was a one-time occurrence, it is a warning for the future of the grave consequences of suboptimal practice in appointments, and how it undermines the primary promises of managerial participation.

What stands out in the case of the EASA’s indirect managerial participation is that access to timely and adequate information is indeed crucial for the credibility and effectiveness of all subsequent stages of participation (debate and input) and of the overall quality of deliberation (i.e. the difference that participation make in terms of the primary promises). This supports the earlier assumption79 that the relevance of the provision of information to a participatory forum is analogous to the right of access to a file in administrative adjudication, as it furthers understanding of the evidentiary basis of the agencies’ operation (in this case the management). Thus, it may be argued that the untimely provision of information to the EASA Advisory Board hinders the accomplishment of the intended promises, especially the promise of more informed managerial outcomes, transparency of the agency’s management and monitoring of budgetary matters. On the whole, the empirical evidence showed that the furthering of the primary promises is inadequate in practice and there is clearly room for improvement in this respect. This failure could be easily

---

79 See Chapter 2, Section 2.3.2.
addressed by a change in the EASA practices (i.e. timely submission of information), which would enhance the overall potential of the Advisory Board.

Leaving aside the practical deficiencies identified, the relevance of managerial participation cannot be dismissed. To this extent, it may also be argued that the concerns that managerial participation “presents a number of shadows” and “may give place to neo-corporative [mode] of governance, whose effects are far from clear” are unfounded in the instance of the EMA and the EASA.\textsuperscript{80} In the case of the EMA, participation in the management board is limited to the representatives of societal interests who participate in their personal capacity and are subject to detailed conflict of interest requirements (which arguably fosters the EMA independence and prevents the risk of capture). Moreover, as shown, the tasks of interest representatives in the EMA management board are clearly delineated and the intended promises of their involvement are straightforward. While the interest representatives in the EMA management board do not perform a role that is fundamentally different from that of other members of the board (i.e. Member States’ representatives), it may nevertheless be argued that their involvement in the management creates some “pressure” on the agency to pay attention to the societal concerns. Besides, it makes it more difficult for the EMA to ignore the issues that might affect interested parties. In the case of the EASA, interested parties (including the industry) do not participate in the agency’s management directly and they do not have access to more “delicate” managerial tasks (e.g. the selection of the executive director). Additionally, the views of the EASA Advisory Board are not binding on the agency, which it is assumed furthers the EASA independence and diminishes the risks of capture. However, it is argued that consultations with the Advisory Board promote the effectiveness of managerial decision-making in the sense that they bring the EASA closer to the “reality” in which it operates.